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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/006,797 | 12/04/2001 | John David Fraser | 55503-002001 | 9884 |

69713 7590 12/22/2008

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| EXAMINER | |
|---|---|
| JUEDES, AMY E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 12/22/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/006,797 | FRASER ET AL. | |
| | Examiner | Art Unit | |
| | AMY E. JUEDES | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2-6,10,11,13,15-18,21-38 and 40-45* is/are pending in the application.

4a) Of the above claim(s) *17,18,21-38 and 40-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6,10,11,13,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 9/12/08 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/12/08 has been entered.

Claims 2 and 5-6 have been amended.
Claim 39 has been cancelled.
Claims 2-6, 10-11, 13, 15-18, 21-38 and 40-45 are pending.

Claims 17-18, 21-38, and 40-45 stand withdrawn from further consideration pursuant to 37 CFR 1.14209 as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Claims 2-6, 10-11, 13, and 15-16 are under examination.

2. The rejection of claims under 35 U.S.C. 112 first paragraph for new matter is withdrawn in view of Applicant's amendment to the claims.

3. The following are new grounds of rejection.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2—6, 10-11, 13, and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamoaoka e al, 1998, Infection and Immunity, vol. 66 pp. 5020-5026 (of record), as evidenced by Nestle et al., 1998.

Yamaoka et al. teach a mutated superantigen comprising mutations only in the T cell receptor binding site (see materials and methods and page 5022 in particular). Said mutated superantigen is coupled to an antigen (GST, see pg 5022

paragraph 1). Furthermore, said mutated superantigen is derived from SPE-C, (see pg. 5020, materials and methods). Yamaoka et al. teach mutating the superantigen by amino acid substitution, resulting in a non-functional (i.e. "deleted") T cell receptor binding site. Yamaoka et al. also teach that the superantigen is reversibly coupled to a protein (GST can be cleaved off - see pp. 5022 paragraph 1). Yamaoka et al. also teach a solution comprising the superantigen in PBS (i.e. a pharmaceutically acceptable carrier, see page 5021 in particular). The instant claims recite that the superantigen conjugate is "effective in antigen presentation". Given it broadest reasonable interpretation, "effective in antigen presentation" might merely require that the conjugate is capable of being processed by an APC. As evidenced by Nestle et al., soluble protein antigens are capable of being taken up and processed by APC. Thus, the protein superantigen/GST conjugate of Yamaoka et al. is inherently "effective in antigen presentation".

Thus, the reference clearly anticipates the invention.

Applicant's arguments filed 9/12/08 have been fully considered, but they are not persuasive.

Applicant argues that Yamaoka et al. teach that GST is fused to the N-terminal of the superantigen, which interferes with the ability of the superantigen to bind to MHC class II. Applicant further notes that as taught by Abbas et al., binding of peptides to MHC is a prerequisite for presentation to T cells. Thus, Applicant concludes that since the superantigen conjugate f Yamaoka et al. does not bind to MHC class II, it is not effective in antigen presentation.

The fact that the conjugate of Yamaoka et al. would not bind to MHC is not relevant, since the conjugate does not present antigen by directly binding to MHC. Rather, the superantigen binds to MHC to facilitate internalization of the conjugate, and processing of the conjugated antigen by the APC. Thus, any protein which can be processed by an APC is "effective in antigen presentation". While the ability to bind to MHC might enhance the processing of the conjugate, it is well known that APCs are capable of non-specifically internalizing and processing any soluble protein antigen, for example after phagocytosis (see Nestle et al., 1998, page 765 in particular). Thus, the protein conjugate of Yamaoka et al., though not able to directly bind to MHC class II, is nevertheless capable of

being taken up and processed by APCs (i.e. is "effective in antigen presentation", as recited in the instant claims).

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 6am - 2pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy E. Juedes
Patent Examiner
Technology Center 1600

/G.R. Ewoldt/
Primary Examiner, Art Unit 1644